

UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

MARK AMMEND, et al.,

Plaintiffs,

v.

BIOPORT, INC. and ROBERT C. MYERS,

Defendants.

Case No. 5:03-CV-31

Consolidated with: 1:03-CV-254

1:03-CV-809

1:05-CV-182

HON. GORDON J. QUIST

OPINION

I. Background

On March 31, 2004, this Court entered an Opinion and Order: (1) granting the State Agency Defendants' (Michigan Department of Public Health and the Michigan Biologic Products Institute) motion to dismiss; (2) granting in part and denying in part Defendant BioPort Inc.'s motion to dismiss; and (3) granting in part and denying in part Defendant Dr. Robert C. Myers' motion to dismiss. The Opinion, which is reported at 322 F. Supp. 2d 848, and the Order initially applied to three consolidated cases, *Allaire, et al. v. BioPort, et al.*, No. 1:03-CV-254; *Fleming, et al. v. BioPort, et al.*, No. 1:03-CV-809; and *Ammend, et al. v. BioPort, et al.*, No. 5:03-CV-31. They were subsequently made applicable to two other later-consolidated cases, *Suk v. BioPort, et al.*, No. 1:04-CV-218, and *Reid, et al. v. BioPort*, No. 1:05-CV-182.¹ Among other things, the Opinion and Order dismissed Plaintiffs' federal constitutional claims for failure to state a claim and dismissed their fraud claim based upon Plaintiffs' retraction of that claim at the hearing held on December 3, 2003.

¹Case No. 1:04-CV-218 was subsequently dismissed pursuant to a notice of dismissal dated December 20, 2004, and signed by counsel for all parties.

See 322 F. Supp. 2d at 870-73. Specifically with regard to BioPort, the Court held that: (1) although BioPort could not be held liable as a successor under a continuity of enterprise theory, BioPort may have assumed liability under the Asset Purchase Agreement for at least some lots of anthrax vaccine and a question of fact remained regarding BioPort's liability based upon its participation in the supplemental testing program, see id. at 864-70; (2) BioPort did not inherit the state's sovereign immunity under the Eleventh Amendment, see id. at 873; (3) questions of fact remained regarding the application of Michigan's drug manufacturer products liability immunity statute, both with regard to the FDA approval and labeling requirements and with regard to the exception for withholding or misrepresenting information, see id. at 873-77; (4) the Feres doctrine (Feres v. United States, 340 U.S. 135, 71 S. Ct. 153 (1950)) does not apply in this case, see id. at 877; and (5) questions of fact remained with regard to all three prongs of the government contractor defense, see id. at 877-79. With regard to Dr. Myers, the Court held that: (1) he was entitled to Eleventh Amendment immunity from the claims against him in his official capacity, see id. at 862-63; and (2) questions of fact remained regarding his entitlement to absolute immunity from personal liability on Plaintiffs' state law claims, see id. at 863-64.

Dr. Myers and BioPort have filed motions for summary judgment in which they contend that they are entitled to judgment on all of Plaintiffs' claims. The issues raised in the motions relate to whether BioPort's and Dr. Myers' affirmative defenses – the focus of the "Stage I" bifurcation set forth in the Court's November 5, 2004, Case Management Order – preclude or limit their liability on Plaintiffs' claims. In its motion, BioPort asserts that it is entitled to summary judgment because, among other things, the Michigan drug manufacturers immunity statute and the governmental contractor defense provide independent and absolute defenses to Plaintiffs' claims. Dr. Myers

asserts that he is separately entitled to summary judgment because he is immune from liability for his actions during his tenure as the highest executive official for biologics operations for the State of Michigan or, alternatively, he is immune because he committed no “gross negligence” as defined by statute, and because Plaintiffs have failed to identify any tortious act by Dr. Myers that caused them injury. For the reasons set forth below, the Court will grant both motions and dismiss these cases with prejudice.

III. Discussion

The pertinent background facts of these cases are adequately set forth in the March 31, 2004, Opinion, and the Court thus finds it unnecessary to reiterate them in this Opinion. The Court notes that in support of their instant motions, BioPort and Dr. Meyers have each provided detailed and supported statements of undisputed facts (“SUF”). Although the Court finds it unnecessary to recount those facts in order to rule on the motions, the Court will refer to such SUFs where appropriate.

A. Dr. Myers’ Motion

As noted above, one of the issues left open in the March 31, 2004, Opinion was whether Dr. Myers is entitled to absolute immunity from personal liability on Plaintiffs’ state law claims. Specifically, the Court found that there were questions regarding whether Dr. Myers was the highest executive official of the Michigan Department of Public Health’s (“MDPH”) Division of Biologic Products and, later, the Michigan Biologic Products Institute (“MBPI”), and questions regarding the scope of his jurisdiction and authority in these positions. Dr. Myers has answered these questions by showing that he was the highest executive official, as both Chief of the Division of Biologic Products at MDPH and as the head of MBPI, as designated in Governor Engler’s Executive Order

creating the MBPI. (Meyers SUF ¶¶ 3-5, 9-14.) In addition, in his position with MDPH and, later, with MBPI, Dr. Meyers was acting within the scope of his executive authority at all times relevant to Plaintiffs' claims. (*Id.* ¶¶ 17-18.) Recognizing these facts, Plaintiffs state that they "concede, as they must, that discovery has revealed that Dr. Myers enjoys immunity against the plaintiffs' claims." (Pls.' Omnibus Mem. Resp. at 11.)

As for Dr. Myers' individual liability for acts that he performed at BioPort, Dr. Myers, as an agent or officer of BioPort, can be held liable for torts committed by BioPort only if he personally committed the tort. See Hartman & Eichhorn Bldg. Co. v. Dailey, 266 Mich. App. 545, 549, 701 N.W.2d 749, 752 (2005) ("It is a familiar principle that the agents and officers of a corporation are liable for torts which they personally commit, even though in doing so they act for the corporation, and even though the corporation is also liable for the tort."). During his tenure at MDPH, MBPI, or BioPort, Dr. Myers did not make any intentional misrepresentation to anyone regarding the anthrax vaccine ("AVA"), nor did he fail to perform his job responsibilities with due care. (Myers SUF ¶¶ 21, 22.) Plaintiffs do not even address Dr. Myers' liability for tortious acts while he was an employee or agent of BioPort, and they fail to point to any evidence that would provide a basis for imposing liability upon Dr. Myers. Accordingly, Dr. Myers is entitled to summary judgment on all claims.

B. BioPort's Motion

Although it raises other issues in its motion, the primary bases for BioPort's motion are that it is immune from liability under the Michigan drug manufacturers immunity statute and that the government contractor defense relieves it of any liability. The Court previously held that questions

of fact remained with regard to both of these defenses. Like Dr. Myers, however, BioPort has now sufficiently answered those questions.

The Michigan drug manufacturers immunity statute provides:

- (5) In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller. However, this subsection does not apply to a drug that is sold in the United States after the effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
 - (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act...and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

M.C.L. § 600.2946(5). As the Court has noted, the statute immunizes a drug manufacturer from liability if the Food and Drug Administration (“FDA”) approved the drug and the drug was properly labeled. See 322 F. Supp. 2d at 876. The statute provides two exceptions to the grant of immunity: (1) where the manufacturer intentionally withholds certain information from, or misrepresents such information to, the FDA, and the FDA would not have approved the drug or would have withdrawn approval had it been fully informed; or (2) where the manufacturer bribes an FDA official for the purpose of obtaining approval of the drug. See Taylor v. Smithkline Beecham Corp., 468 Mich. 1, 7, 658 N.W.2d 127, 131 (2003). In Garcia v. Wyeth-Ayerst Laboratories, 385 F.3d 961 (6th Cir. 2004), a decision issued subsequent to the Court’s March 31, 2004, Opinion, the Sixth Circuit held that the exceptions to immunity apply only if the FDA itself (or through another federal agency)

determines that the manufacturer has defrauded or bribed the FDA. See id. at 967. Thus, a plaintiff may not establish the exceptions through proof of fraud or bribery, but instead must show that the FDA has made its own determination of fraud or bribery. See id.

BioPort has shown that the FDA approved the AVA in connection with the issuance of the license to MDPH, MBPI, and BioPort to produce the vaccine and that the FDA continuously inspected the production facilities for compliance and reviewed and approved changes to production facilities and equipment. (BioPort SUF ¶¶ 13, 17, 44, 46, 48, 58, 59, 64, 79, 85, 107.) The FDA also monitored and approved various aspects of the AVA supplemental testing procedure and regularly reviewed data pertaining to adverse events. (Id. ¶¶ 122, 134, 137.) Moreover, on October 3, 2000, Mark Elengold, Deputy Director of Operations of the FDA's Center for Biologics Evaluation and Research ("CBER"), testified before the United States House of Representatives' Committee on Government Reform that "FDA believes that previously manufactured and CBER released products, not presently quarantined by BioPort, are safe and effective for the labeled indication." (Id. ¶ 130.) In addition, the AVA was properly labeled. (Id. ¶ 155.) Plaintiffs have failed to present any evidence suggesting that the FDA did not approve the vaccine or that the vaccine was not properly labeled. Nor have Plaintiffs presented any evidence supporting the application of the above-mentioned exceptions, namely, a determination of fraud or bribery by the federal government.

Although Plaintiffs recognize that the undisputed facts support entry of summary judgment if the Court applies Garcia in this case, they argue that the Court should not apply that case because it was decided after this case was filed and, in any event, it would be unfair. These arguments are rejected. Plaintiffs fail to cite any authority to support their argument that Garcia should not apply because it post-dates the filing of this case. In fact, the rule is that "courts generally apply the law

existing at the time of the decision.” Patel v. Gonzales, 432 F.3d 685, 690 (6th Cir. 2005); see also Lund v. Shearson/Lehman/Am. Express, Inc., 852 F.2d 182, 183 (6th Cir. 1988) (stating that “we begin with the assumption that the rule of law in force at the time a decision is rendered is the law to be applied”). Plaintiffs fail to explain why the general rule of retrospective application should not apply to the Sixth Circuit’s decision in Garcia. Moreover, even if the Court for some reason were to accept Plaintiffs’ argument, Plaintiffs have made no effort to present any evidence to establish either fraud or bribery. Finally, while Plaintiffs may rightfully believe that it is unfair that Michigan has decided to grant drug manufacturers broad immunity from liability in certain situations, they have failed to cite any authority upon which this Court could reject the application of controlling law as “unfair.”

A defendant may avoid liability on state-law claims under the government contractor defense by showing the following: (1) that the United States government approved reasonably precise specifications; (2) that the product conformed to those specifications; and (3) the contractor must warn the United States government about dangers associated with the use of the product known to the manufacturer but not to the government. See Boyle v. United Techs. Corp., 487 U.S. 500, 512, 108 S. Ct. 2510, 1518 (1987). BioPort has made all of these showings. First, BioPort has shown that the Department of Defense (“DoD”) not only approved “reasonably precise” specifications, but that agents of the DoD actually invented and patented AVA. (BioPort SUF ¶¶ 2, 3.) The DoD then retained a contractor, Merck, Sharp & Dohme, to develop a manufacturing process for large scale production of AVA using an anaerobic culture method. (Id. ¶ 4.) Thereafter, DoD formed its relationship with MDPH, MBPI, and, ultimately BioPort, when it approached MDPH for assistance in refining and standardizing the manufacturing process and in establishing a manufacturing facility.

(*Id.* ¶ 6.) DoD remained intimately involved in all aspects of the manufacturing process, even to the extent that a DoD official characterized BioPort as a “GOCO,” meaning a “government owned, contractor operated” organization. (*Id.* ¶ 98.) Thus, BioPort manufactured AVA according to the DoD’s very precise specifications. Second, BioPort has shown that MDPH, MBPI, and BioPort manufactured AVA in conformity with the DoD’s standards. The DoD’s procedure was to accept a lot of the vaccine only after it was released by the FDA pursuant to certain protocols that insured that each lot of vaccine had passed a number of tests. (*Id.* ¶¶ 107, 109.) Moreover, with regard to the lots in DoD’s stockpile, DoD used only those lots that passed the supplemental testing protocol. In addition, there is no evidence that DoD has ever asserted that any of the AVA that it used to inoculate military personnel failed to meet its specifications. Finally, BioPort has shown that the third requirement is met, i.e., that DoD was fully aware of all risks related to the use of AVA, because DoD, as the primary user of AVA, is at least as knowledgeable, if not more so, than BioPort regarding such risks. (*Id.* ¶¶ 132, 144, 146, 149, 151-52.) In addition, DoD was well aware of the risks or dangers identified by the FDA in its inspections of BioPort’s facilities. (58-59, 64-68, 86, 91.)

Plaintiffs fail to cite any evidence contradicting BioPort’s evidence. In fact, the only evidence they cite is Dr. Myers’ testimony, which they admit is consistent with BioPort’s evidence and defense. (Pls.’ Omnibus Mem. Resp. at 13.) Although they admit that there is sufficient evidence to support BioPort’s request for summary judgment on the government contractor defense, they assert that the Court must determine whether or not Dr. Myers’ testimony and the other evidence is sufficient to overcome Plaintiffs’ “allegations.” (*Id.*) Plaintiffs’ reliance upon their allegations in their complaint to defeat BioPort’s motion for summary judgment is unavailing. “It

is beyond cavil that the adverse party on summary judgment may not simply rely on the allegations of its pleadings, but must present affirmative evidence by way of either affidavit or deposition, *i.e.*, sworn testimony, sufficient to show that material facts are genuinely in issue.” Crown Serv. Plaza Partners v. City of Rochester Hills, Nos. 98-1581, 98-1666, 2000 WL 658029, at *6 (6th Cir. May 8, 2000); Bennett v. P/O Schroeder, 99 F. App’x 707, 717 (6th Cir. 2004) (stating that “at the summary judgment stage . . . Plaintiff can no longer simply rely on the allegations in his complaint; rather, he must ‘present affirmative evidence’ supporting his allegations in order to withstand summary judgment”). Accordingly, Plaintiffs have failed to present any evidence showing that a genuine issue of material fact remains with respect to BioPort’s reliance on the government contractor defense.²

IV. Conclusion

Based upon the foregoing, the Court will grant Dr. Myers’ and BioPort’s motions for summary judgment.

An Order consistent with this Opinion will be entered.

Dated: April 19, 2006

/s/ Gordon J. Quist
GORDON J. QUIST
UNITED STATES DISTRICT JUDGE

²Because the Court has concluded that BioPort is entitled to summary judgment based upon the Michigan drug manufacturer liability statute and upon the government contractor defense, it need not address BioPort’s other arguments.